



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/367,950 08/18/99 EKSTROM T 06275/188001

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HM12/1218

EXAMINER

KIM, J

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

12/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/367,950

Applicant(s)

EKSTROM, TOMMY

Examiner

Jennifer M Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Claims 13-24 are presented for examination.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13-15, 17-18, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. (WO 93/11773) of record.

3. Carling et al. at page 8-14, page 3, line 35 through page 4, line 10, lines 30-35, page 6, lines 5-30, and page 7, lines 1-5, teach a composition comprising Applicant's active agents use for treating respiratory disorder such as asthma set forth in claims 13-15, 17-18, 20-21, and 23.

4. Carling et al. at page 4, lines 3-10, also teach that the combination of formoterol and budesonide has not only a greater

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efficiency and duration of bronchodilator action but a rapid onset of action.

5. The difference between Carling et al. and Applicant's invention is a specific carrier set forth in claim 24, the molar ratio of active agents set forth in claim 14, and the particle size set forth in claim 22.

However, the molar ratio of active agents to be used, the selection of carrier, and the particle size of active agents are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. (WO 93/11773) of record in view of Hett et al. (Org. Process Res. Dev., 1998) and Ryrefeldt et al. (Biochem. Pharmacol., 1989).

See paragraph 3, above, for teachings of Carling et al.

Hett et al. teach at the abstract that (R,R)-Formoterol is a long-acting, very potent β -agonist, which is used as a bronchodilator in the therapy of **asthma**.

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Ryrfeldt et al. teach at the abstract that 22R epimer of **budesonide** is more potent in the treatment of bronchial asthma than 22S epimer.

The claims differ from the cited references in claiming a combination of (R,R)-Formoterol, and **budesonide**, (claim 16) and a combination of Formoterol and 22R epimer of **budesonide** (claim 19) to treat asthma. To employ combinations of (R,R)-Formoterol, and **budesonide**, (claim 16) and a combination of Formoterol and 22R epimer of **budesonide** (claim 19) to treat asthma would have been obvious because both components are well known, and potent active agents individually for treating asthma. It would be expected that the combination of components would treat asthma.

The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069 (CCPPA 1980)).

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For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Theodore J. Criares
Primary Examiner
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jmk

December 5, 2000